

REMARKS/ARGUMENTS

Claims 1, 3-8, 10-17 and 19-23 are pending in the application. Claims 2, 9, and 18 have been canceled without prejudice or disclaimer. New claims 19 through 23 have been added; however, no additional claims fees are necessary. No new subject matter has been added.

Claim Rejections 35 USC § 112, first paragraph

Claims 1 through 18 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. Independent claims 1 and 17 include the limitation "...of a partial DNA sequence." Further, claim 18 has been canceled. Therefore, the pending 35 USC 112, first paragraph rejection is believed to be obviated for independent claims 1 and 17 and the claims which depend therefrom. Thus, removal of the pending rejection is respectfully requested and allowance solicited.

Claim Rejections 35 USC § 112, second paragraph

Claims 1 through 18 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses.

Claims 1, 17, and 18 have been asserted to be indefinite for the limitation of "sequencing said genome into its DNA sequence." Claims 1 and 17 no longer include such limitation and claim 18 has been canceled. Thus, it is Applicant's belief that the pending rejection is obviated and the removal of such rejection is respectfully requested.

Claim 4 has been asserted to be indefinite because of the phrase "updating said searching for at least one additional medical condition associated with said DNA sequence." Claim 4 includes the limitation of "updating being performed each time a

DNA fragment is submitted to the database.” Therefore, removal of the pending Section 112, second paragraph rejection is respectfully requested.

Claim 6 has been asserted to be indefinite for the phrase “said tracking” lacks a clear antecedent basis. Claim 5 includes the limitation of “tracking discoveries of genetic variations associated with said at least one additional medical condition.” Thus, it is Applicant’s belief that Claim 6 is definite and thereby it is respectfully requested that the present Section 112, second paragraph rejection be removed.

Claim 10 has been asserted to be indefinite for the phrase “said information” lacks a clear antecedent basis. Claim 10 includes the limitation of “additional information relating to said at least one medical condition comprises.” As such, Applicant believes that Claim is definite and respectfully requests removal of the pending Section 112, second paragraph rejection.

Claims 13 and 14 have been asserted to be indefinite for the phrase “said information” lacks a clear antecedent basis. Claim 13 and 14 includes the limitation of “said information relating to said at least one medical condition.” Thus, Applicant believes that Claims 13 and 14 are definite and respectfully requests removal of the pending Section 112, second paragraph rejection.

Claim 14 has been asserted to be indefinite for the phrase “the health specialist” lacks clear antecedent basis. Claim 14 depends from claim 13 which includes the limitation of “communicating said information relating to said at least one medical condition to a health specialist” imparting antecedent basis to the phrase “the health specialist” in claim 14. Therefore, removal of the pending Section 112, second paragraph rejection is respectfully requested.

Claim 18 has been asserted to be indefinite for the phrase “said information” lacks a clear antecedent basis. Claim 18 has been canceled. As such, Applicant believes that the pending Section 112, second paragraph rejection is obviated and respectfully requests the removal of such rejection.

Claim Rejections – 35 U.S.C. § 102

35 U.S.C. § 102(a)

Claims 1-3, 8, 10, 12-13, 16, and 18 stand rejected under 35 U.S.C. 102(a) as being anticipated by Patel et al. (American Journal of Ophthalmology, Vol. 129, pages 258-260, Feb. 2000) hereinafter referred to as Patel. Applicant respectfully traverses.

The present invention provides a method for providing and updating customized health care information to an individual based, at least in part, on the genetic blueprint provided by that individual's DNA. In particular, information regarding an individual's pre-disposition to medical conditions known to be associated with specific DNA sequence fragments is provided. Such process is beneficial for it allows an individual to determine his or her pre-disposition to such conditions prior to such conditions manifesting physical symptoms. Thus, the present method allows an individual to take preventive measures.

Independent Claim 1 includes the limitation of "submitting a partial DNA sequence isolated from the individual to which customized health care information is to be provided to a customized healthcare information provider." In addition, claim 1 includes the limitation of "analyzing said DNA sequence, analysis including comparing the partial DNA sequence to a plurality of DNA fragments stored on a database for identifying a plurality of medical conditions, each DNA fragment included within the plurality of DNA fragments being associated with at least one medical condition." Neither of the aforementioned limitations is taught by Patel. As the Office is well aware:

In order to prove a *prima facie* case of anticipation, "a single prior source must generally contain all of the essential elements of the claim." *W.L. Gore & Assoc. v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Further, "the

prior art reference must disclose each element of the claimed invention arranged as in the claim.” *Lindermann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added).

Applicant asserts that Patel fails to disclose a method for providing and updating customized health care information to an individual based on a partial DNA sequence isolated from that individual as defined by the instant application. For example, claim 1 recites “submitting a partial DNA sequence isolated from the individual to which customized health care information is to be provided to a customized healthcare information provider.” Patel discloses a method of obtaining and providing genetic information for an individual relating to a single medical condition, von Hippel-Lindau syndrome. Patel does not teach the submission of a partial DNA sequence to a customized healthcare information provider. Further, no where does Patel teach or suggest “analyzing said DNA sequence, analysis including comparing the partial DNA sequence to a plurality of DNA fragments stored on a database for identifying a plurality of medical conditions, each DNA fragment included within the plurality of DNA fragments being associated with at least one medical condition.” In contrast, Patel is only accessing genetic information for a single medical condition, von Hippel-Lindau disease, not a plurality of medical conditions as in the claimed invention. The claimed invention is beneficial for it provides an individual information regarding his or her predisposition to a wide range genetically based diseases. As the Office is aware, anticipation cannot be established when “the prior art is lacking or missing a specific feature or the structure of the claimed invention.” *Lindermann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (emphasis added). Therefore, a *prima facie* case of anticipation has not been established. Applicants respectfully request the removal of the pending 35 U.S.C. §102(a) rejection.

Claim Rejection 35 U.S.C. § 103

35 U.S.C. § 103(a)

When applying 35 U.S.C. §103, the following tenets of patent law must be adhered to: (A) the claimed invention must be considered as a whole; (B) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) reasonable expectation of success is the standard with which obviousness is determined. *See MPEP § 2141 and Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 220 USPQ 182, 187 n.5 (Fed. Cir. 1986).

Claims 4-7, 9, 11, 15, and 17, stand rejected under 35 U.S.C. §103(a) as being unpatentable over Patel et al. (American Journal of Ophthalmology, Vol. 129, pages 258-260, Feb. 2000) hereinafter referred to as Patel in view of Beroud et al. (Nucleic Acids Research, Vol. 26, pages 256-258, 1998) hereinafter referred to as Beroud. Applicant respectfully traverses.

As noted in the pending 35 U.S.C. §102(a) rejection, Patel fails to disclose each and every limitation included in Claim 1 from which claims 4, 7, 11, and 15 depend including “submitting a partial DNA sequence isolated from the individual to which customized health care information is to be provided to a customized healthcare information provider” and “analyzing said DNA sequence, analysis including comparing the partial DNA sequence to a plurality of DNA fragments stored on a database for identifying a plurality of medical conditions, each DNA fragment included within the plurality of DNA fragments being associated with at least one medical condition.” Further, Patel fails to disclose each and every limitation included within Claim 17 including “submitting a partial DNA sequence isolated from the individual to which customized health care information is to be provided to a customized healthcare information provider,” “interpreting said partial DNA sequence to identify medical conditions associated with said partial DNA sequence, interpreting

including comparing said partial DNA sequence with a plurality of DNA sequence fragments known to be diagnostic of specified medical conditions,” and “updating said interpretation of said partial DNA sequence, updating being performed each time a DNA sequence fragment known to be diagnostic of specified medical conditions is added to the comparison.” Beroud fails to correct these defects.

First, Beroud does not teach or suggest the providing of a partial DNA sequence to a customized healthcare information provider. Nowhere in Beroud is the use of a customized healthcare information provider mentioned. Further, Beroud provides software and a database for the analysis of mutations in a single gene (the VHL gene). Here, the claimed invention includes analyzing a plurality of DNA sequences fragments associated with a plurality of medical conditions. Such feature is beneficial for an individual often does not know which sequences and medical conditions to analyze. For example, an individual may not know which genetic diseases/medical conditions he or she may be pre-disposed to acquiring. Therefore, the combination of Patel in view of Beroud, on the whole, fails to teach the present invention. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Ryoka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). *See also In re Wilson*, 165 U.S.P.Q. 494 (C.C.P.A. 1970). Emphasis added. Removal of the pending rejection under 35 U.S.C. §103(a) to Claims 4-7, 11, 15, and 17 is requested and allowance is earnestly solicited.

New Claims

Claims 19 through 23 have been added to present application. No new subject matter is added. Support for the claims may be found throughout the specification and drawings as filed. For example, support for Claims 19 and 20 may be found in FIG. 1 and throughout the specification as filed. Further, support for claim 21 stems from at least FIG. 1, and generally claim 13 as originally filed. Additionally, claims 22 and 23 find support from at least FIG. 2 and the specification, particularly pages 12 through 14. Moreover, no additional search is required as the scope of the newly added claims falls within the initial search scope.

CONCLUSIONS

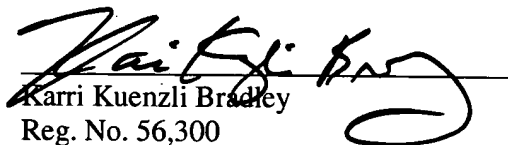
Applicant has made an earnest attempt to place this case in condition for allowance. For the foregoing reasons and for other reasons clearly apparent, Applicant respectfully requests reconsideration and full allowance of all claims.

If the Examiner feels that a telephone conference or an interview would advance prosecution of this Application in any manner, the undersigned attorney for Applicants stands ready to conduct such a conference at the convenience of the Examiner.

Respectfully submitted,
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